| 1 | 2 | 3 | 4 | 5 |
|---|---|---|---|---|
| 4. | Arterolane Maleate + Priperaquine Phosphate (Fixed Dose) | II | Ranbaxy | Bangkok, Rourkela, Jamshedpur |
| 5. | AS+MQ (Artesunate +Mefloquine) (Fixed Dose) | III | DNDi | Goa, Mangalore |
| 6. | Pyramax for *P. vivax* (Fixed Dose) | III | MMV, Shinphong | Mangalore |
| 7. | Pyramax for *P. falciparum* | III | MMV, Shinphong | Mangalore |

**Infant deaths due to clinical trials**

93. SHRI N.R. GOVINDARAJAR: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that forty-nine infants died at AIIMS while being subjected to clinical trials for testing new drugs and therapies over the last two and a half years;

(b) if so, the details thereof;

(c) whether foreign manufactured medicines were listed during the trials;

(d) if so, the details thereof;

(e) how many children were admitted for these clinical trials and how many sets of trials were conducted on these children;

(f) whether the parents of these children were well informed about these clinical trials and were given social counseling before these trials; and

(g) if so, the details thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) Death of 49 children enrolled in 6 clinical trials at All India Institute of Medical Sciences, New Delhi was reported between January 2006 and June, 2008. These consisted of 4 clinical trials with drugs as interventions, one trial with feeding protocol and one with Continuous Positive Airway Pressure (CPAP). It was observed that 4142 children were enrolled in 42 clinical trials in the Department of Paediatrics.

(c) and (d) Yes, Sir. In one case, the foreign manufactured medicines were used during the trials. Zinc deficiency is of public health importance in India because of the problem of widespread zinc deficiency. WHO/UNICEF, Indian Academy of Pediatrics and the National Rural Health Mission, Govt. of India recommend use of zinc in treatment of acute diarrhea in all infants and children. This policy is based on large well done randomized controlled studies from many

developing countries, and different parts of India including AIIMS. Zinc is important in human biology and its deficiency impairs various immune and non immune defence against infections. Low levels of zinc in the cord blood and in infants, particularly so in the low birth weight, who constitute one-third of all births in India and contribute maximally to the increased infant deaths. Neonatal sepsis is an important cause of death in these infants. The intent of the study was to provide a cheap, safe and efficacious treatment in addition to antibiotics for serious bacterial infection in neonates and young infants. The Government of India has been encouraging the public sector companies and the drug industry to prepare cheap dispersible zinc tablets. The Lancet has rated use of zinc in sick children in diarrhea as one of the 10 essential interventions for all child health programmes in the developing world.

(e) 1073 children were admitted for these clinical trials and 42 clinical trials were conducted on these children.

(f) and (g) Yes, Sir. The parents of these children were counselled before these trials and written consent were obtained from the parents/guardians of the children.

**Mercury-based medical equipments**

94. SHRI B.J. PANDA:
MS. MABEL REBELLO:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government is aware that mercury-based instruments especially in the health-sector continue unchecked and it is posing an unabated serious threat to the medicos' health; and

(b) if so, what is the action plan of Government to address this issue?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRIMATI PANABAKA LAKSHMI): (a) and (b) In so far as Central Government Hospitals in Delhi are concerned, no case of serious threat to the medicos' health has been brought to the notice of the Ministry due to the use of mercury-based instruments. These hospitals have already taken steps to phase out the mercury based equipments gradually to reduce environmental pollution with mercury waste Awareness Campaigns and Training of the health care givers including the maintenance staff on safe handling and reduction of use of mercury based equipments have started. These hospitals also follow the guidelines laid down in the Bio-Medical Waste (Management and Handling) Rules, 1998, as amended in 2000 and 2003.

**Smoking expenditure**

†95. MS. SUSHILA TIRIYA:
SHRI MOTILAL VORA:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

†Original notice of the question was received in Hindi.